

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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CHRISTEL BILLHOFER, On Behalf of  
Herself and All Others Similarly  
Situated,

07 Civ. 9920

Plaintiff,

OPINION

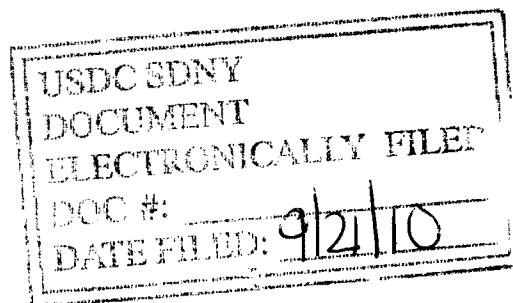
-against-

FLAMEL TECHNOLOGIES, S.A., STEPHEN H.  
WILLARD, and RAFAEL JORDA,

Defendants.

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A P P E A R A N C E S:



Attorneys for Plaintiff

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**Sweet, D.J.**

Lead Plaintiff Christel Billhofer ("Billhofer") has moved to withdraw from this action and, pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA") and presumably Rule 21, Fed. R. Civ. P., to substitute named plaintiff George Jenkins ("Jenkins") as Lead Plaintiff in this action and to amend the Case Management Order. Defendant Flamel Technologies, S.A. ("Flamel" or the "Defendant") has opposed the motion on the grounds that the substitution also requires a further amendment of the complaint under Rule 15, Fed. R. Civ. P., an amendment which Flamel contends is precluded as a consequence of initial discovery. Upon the conclusions set forth below, the motion is granted and the Case Management Order is amended.

### **Prior Proceedings**

In 2007, Billhofer filed this putative class action alleging securities fraud. On March 27, 2008, she amended her complaint. Flamel moved to dismiss, and on October 5, 2009, the Honorable Charles Haight issued an opinion denying the motion.

Billhofer v. Flamel Techs., SA, 663 F. Supp. 2d 288, 304

(S.D.N.Y. 2009) (the "October 5 Opinion").

The amended complaint in this action (hereinafter "Complaint" or "Compl.") asserts claims against Flamel and two of its officers, Stephen H. Willard and Rafael Jorda, under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934. It alleges that Flamel made materially misleading statements about the anticipated commercial success of COREG CR, a drug developed by GlaxoSmithKline ("GSK") that is used in the treatment of heart failure, among other things. (Compl. ¶ 14.) COREG CR was intended to replace COREG IR, which was an "immediate release" drug, requiring patients to take multiple dosages per day. (Id. ¶ 15.) Using Flamel's drug delivery system technology, COREG CR was a "controlled release" version of COREG IR that allowed patients to take the drug only once a day. (Id. ¶ 16.) COREG CR was promoted as an improved and better version of the drug because it would lead to a higher level of "compliance" (i.e., taking and not exceeding the required daily dosage). (Id.)

Sometime prior to March 23, 2007, a clinical trial, known as the CASPER trial, was conducted to measure the differential compliance, quality of life and satisfaction of

patients taking COREG CR as opposed to COREG IR. (Id. ¶ 18.)

On or about August 23, 2007, an abstract describing the results of the CASPER trial was published in the Journal of Cardiac Failure. It suggested that switching from COREG IR to COREG CR did not improve drug-taking compliance, and the price of Flamel's American Depositary Receipts ("ADRs") allegedly fell as a result. (Id. ¶¶ 20-21.)

During the period from March 23 to August 22, 2007 - the proposed class period - Flamel made a number of predictions about the anticipated success of COREG CR. (Id. ¶¶ 22-27.) The Complaint has alleged that these statements were fraudulent, because Flamel allegedly knew about the results of the CASPER trial as of the beginning of the class period. (Id. ¶¶ 17, 28.) Paragraphs 18 and 19 of the Complaint allege the following:

18. In order to prove the benefits of COREG CR, GSK and Flamel commenced a clinical trial to measure the differential compliance, quality of life and satisfaction with medication in chronic heart failure patients taking COREG IR vs. COREG CR (the "Casper Trial"). The primary outcome of the CASPER Trial was pill-taking compliance.

19. By no later than the start of the Class Period, the CASPER Trial was complete and the results were made known to GSK and Flamel. An abstract of the CASPER Trial was required to be submitted to the Journal of Cardiac Failure by no later than April 9, 2007. To meet this deadline, GSK and Flamel

were required to complete the CASPER Trial, analyze the associated data, and draw conclusions therefrom - all sufficiently in advance of the submission date.

(Id. ¶¶ 18-19.)

The October 5 Opinion concluded that the Plaintiff's allegations supported an inference that Flamel "knew something about the CASPER study results at some point during the 'Class Period.'" 663 F. Supp. 2d at 302. In response to Flamel's argument that certain documents identified in the Complaint were consistent with Flamel's being unaware of the CASPER trial results prior to publication, Judge Haight "[did] not find these documents to be indicative one way or the other of Flamel's involvement in the Casper study." Id. at 302 n.15.

According to Flamel, the discovery to date has established "a different story" (Opp. 4-8), and requires the denial of the motion under Rule 15, Fed. R. Civ. P. (Opp. 8-10).

The instant motion was heard on June 9, 2010.

**The Motion Is Granted**

Despite the absence of explicit authorization under the PSLRA or Rule 23, courts have the "ability to consider motions to disqualify, remove, withdraw, substitute, and add lead plaintiffs throughout the litigation of a securities class action." In re NYSE Specialist Sec. Litig., 240 F.R.D. 128, 133 (S.D.N.Y. 2007).

Flamel has not opposed Billhofer's withdrawal, the substitution of Jenkins, or amendment of the Case Management Order. Instead, Flamel contends that Jenkins must now file an amended complaint because, under Rule 15, a "proposed amended complaint must be filed along with the motion for leave to amend." (Opp. 9.) This contention is misplaced, however, because Jenkins seeks to be substituted in as Lead Plaintiff and did not file a motion for leave to amend.

In support of her motion, Billhofer cites many cases in which a lead plaintiff has been substituted in without filing an amended complaint to complete such substitution. See, e.g., In re IMAX Sec. Litig., No. 06 Civ. 6128, 2009 WL 1905033, at \*4 (S.D.N.Y. June 29, 2009) (permitting substitution of lead

plaintiff without filing of amended complaint); In re Williams Sec. Litig., No. 02 Civ. 72, slip op. (N.D. Okla. Jan. 18, 2005) (same); Bridgeport & Port Jefferson Steamboat v. Bridgeport Port Auth., 335 F. Supp. 2d 275, 285 (D. Conn. 2004) (permitting substitution of plaintiff without filing an amended complaint); Donoghue v. MIRACOR Diagnostics, Inc., No. 00 Civ. 6696, 2002 WL 233188, at \*1 (S.D.N.Y. Feb. 11, 2002) (same); Cole v. Am. President Lines, 156 F. Supp. 334, 335 (S.D.N.Y. 1957) (noting substitution of plaintiff with "no change in the complaint").

To support its argument that Jenkins is required to file an amended complaint, Flamel relies on Zito v. Leasecomm Corp., in which the Court denied plaintiffs' motion to amend their complaint so as to add a new defendant and to reinstate claims previously dismissed by the Court, but granted the motion to add a new plaintiff. No. 02 Civ. 8074, 2004 WL 2211650, at \*25-26 (S.D.N.Y. Sep. 30, 2004). Here, however, Billhofer only seeks to change the composition of the plaintiffs, as opposed to reasserting previously dismissed claims or adding defendants. Zito is therefore inapplicable and does not require Jenkins to submit an amended pleading.

Flamel also contends that the limited third-party document discovery received to date has undermined Judge Haight's finding that plaintiff's allegations support an inference of scienter regarding the CASPER study results during the Class Period, and that such an inference "can no longer be asserted in good faith." (Opp. 3.) Accordingly, Flamel argues that Jenkins must amend the complaint now in light of the disputed discovery to date. No authority has been cited for this proposition, and there is authority to the contrary. See, e.g., Curley v. Brignoli Curley & Roberts, Assocs., 128 F.R.D. 613, 616 (S.D.N.Y. 1989) ("There is thus no obligation to update a pleading, motion or other paper based on new information provided that the document met the requirements of Rule 11 when signed."); Samuels v. Wilder, 906 F. 2d 272, 275 (7th Cir. 1990) (holding that "revisions of pleadings" are not required "to conform with newly discovered information" and there is no "continuing obligation on attorneys to reevaluate the merits of the case as the litigation develops" (internal citations and quotations omitted)). Moreover, Billhofer contends that the limited third-party document discovery received to date supports the continuation of the Complaint and does not undermine the inference of scienter. (Reply 6.)



Flamel also contends that an amended complaint should be filed because a party is required to be listed in a caption. (See Opp. 9 n.5.) While that may be the case with ordinary litigation, the lead plaintiff is often not listed in the caption in securities class actions. See, e.g., In re LaBranche Secs. Litig., No. 03 Civ. 8201 (in which investors Anthony Johnson, Clyde Farmer, Edwin Walthall, Donald Stahl and City of Harper Woods Retirement System served as lead plaintiffs and were not listed in the caption); Freudenberg v. E\*Trade Fin. Corp., No. 07 Civ. 8538 (in which investors Kristen Management Ltd., Straxton Properties Inc., Javed Fiyaz and Ira Newman serve as lead plaintiffs and are not listed in the caption).


The October 5 Opinion denying Flamel's motion to dismiss recognized that discovery is necessary to flush out what and when Flamel knew about the CASPER trial results. See Billhofer, 663 F. Supp. 2d at 304. The withdrawal of Billhofer and substitution in of Jenkins as Lead Plaintiff does not alter the need for additional discovery and does require the filing of an amended pleading.

Conclusion

For the foregoing reasons, Billhofer's motion to withdraw as Lead Plaintiff is granted, and Jenkins is substituted as Lead Plaintiff in this action. Submit any opposition to the Proposed Amended Case Management Order within ten days.

It is so ordered.

New York, NY  
September 20, 2010

  
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ROBERT W. SWEET  
U.S.D.J.